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Name: Linda S. Jernigan  
Signature: *Linda S. Jernigan*

P&G Case P142M

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of :  
Chew et al. : Confirmation No.  
Serial No. 10/764215 : Group Art Unit  
Filed January 23, 2004 : Examiner

For Methods And Compositions Utilizing Astaxanthin

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, record is being made on the attached Form PTO/SB08 of documents which the Patent Office may wish to consider in connection with examination of the above-identified patent application. It is respectfully requested that the cited documents be carefully considered by the Examiner and made of record in this case. As provided in §1.97(g), no representation is made or intended that a thorough art search was made. As provided in 37 C.F.R. §1.97(h), this Information Disclosure Statement does not constitute an admission of any kind, and specifically is not an admission that the documents listed on attached form PTO/SB08 are, or are considered to be, material to the patentability of the above-identified patent application, as defined in 37 C.F.R. §1.56(b).

1. ☒ 37 C.F.R. §1.97(b)(1) - U.S. Direct (use when filing IDS with nonprovisional patent application, or with Request for Continued Examination (RCE); or within 3 months of filing a nonprovisional patent application)

This information disclosure statement, submitted under 37 C.F.R. §1.97(b)(1), is being filed with the patent application, with a Request for Continued Examination or within three months of the filing date of a national application. Therefore, no fee is believed to be due.

2. ☐ **37 C.F.R. §1.97(b)(3) - (use when filing IDS more than 3 months after filing a nonprovisional patent application, but prior to receipt of first Office Action)**

This information disclosure statement is being submitted under 37 C.F.R. §1.97(b)(3). Applicants have not received an Office Action on the merits in the present application. Therefore, no fee is believed to be due. However, in the event that this paper is crossing in the mail with a first Office Action on the merits, authorization is hereby given to charge the required fee pursuant to 37 C.F.R. §1.97(c) and 37 C.F.R. §1.17(p) to Deposit Account No. 16-2480 in the name of The Procter & Gamble Company. A duplicate of this letter (or a fee transmittal form) is enclosed to facilitate charging of the fee, if necessary.

3. ☐ **37 C.F.R. §1.97(b)(4) - (use when filing IDS prior to receipt of first Office Action after the filing of a Request for Continued Examination (RCE) under §1.114)**

This information disclosure statement is being submitted under 37 C.F.R. §1.97(b)(4). Applicants have not received a first Office Action after filing a Request For Continued Examination (RCE). Therefore, no fee is believed to be due. However, in the event that this paper is crossing in the mail with a first Office Action on the merits, authorization is hereby given to charge the required fee pursuant to 37 C.F.R. §1.97(c) and 37 C.F.R. §1.17(p) to Deposit Account No. 16-2480 in the name of The Procter & Gamble Company. A duplicate of this letter (or a fee transmittal form) is enclosed to facilitate charging of the fee, if necessary.

4. ☐ **37 C.F.R. §1.97(c) with fee payment - (use when filing IDS after receipt of first Office Action, and before receipt of Final Office Action, Notice of Allowance, or an action that otherwise closes prosecution)**

This information disclosure statement is being submitted under 37 C.F.R. §1.97(c). Applicant(s) have not received a final action under 37 C.F.R. §1.113, a notice of allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in the application (e.g., *Ex parte Quayle*) as of the date of this submission. Applicant(s) elect to pay the fee set forth in 37 C.F.R. §1.17(p). Please charge the fee set forth in 37 C.F.R. §1.17(p) to Deposit Account Number 16-2480 in the name of The Procter & Gamble Company. A duplicate copy of this letter (or a fee transmittal form) is enclosed to facilitate the charging of the fee.

5. ☐ **Information to be Considered with Continued Prosecution Application (CPA) Filing (use when filing IDS with a Continued Prosecution Application (CPA) for Design Case)**. This information disclosure statement is being filed with a Continued Prosecution Application (CPA) filed under 37 C.F.R. 1.53(d).

**ADDITIONAL ITEMS TO BE NOTED BY THE EXAMINER:**

☐ (1) (For use with applications filed prior to or on June 30, 2003.) Copies of the cited documents are enclosed.

OR

☐ (2) (For use with applications filed after June 30, 2003.) In accordance with 37 C.F.R. §1.98(a)(2), Applicants are submitting copies of foreign patent documents and non-patent literature.

OR

☐ (3) All of the cited references were previously cited by or submitted to the USPTO in prior application Case No. \_\_\_\_, U.S. Patent Application Serial No. \_\_, filed \_\_. Applicants claim priority to said application under 35 U.S.C. §120. Accordingly, copies of previously submitted references are not provided with this Statement, pursuant to 37 C.F.R. §1.98(d). It is respectfully requested that the cited documents be carefully considered by the Examiner and made of record in this case.

OR

☐ (4) Copies of all said documents, except Cite Numbers \_\_\_\_, were submitted and considered in parent application U.S. Patent Application Serial No. \_\_\_\_, filed \_\_\_\_\_. Applicant(s) claim priority to said application under 35 U.S.C. §120. Accordingly, copies of previously submitted references are not provided with this Statement, pursuant to 37 C.F.R. §1.98(d). Copies of references not previously submitted are enclosed. It is respectfully requested that the cited documents be carefully considered by the Examiner and made of record in this case.

☐ (5) Pursuant to 37 C.F.R. §1.98(c), a concise explanation of the relevance of each cited reference that is not in the English language is provided.

☐ (6) Applicants also respectfully request the Examiner to consider and make of record the co-pending applications listed on the attached page.

☐ Additional information is attached.

Respectfully submitted,

By

Kelly L. McDow-Dunham  
Attorney or Agent for Applicant(s)  
Registration No. 43,787  
(513) 622-0159

Date: March 18, 2004  
Customer No. 27752

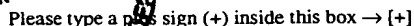
(P142MIDS.doc) (Last Revised 10/10/03)

**CO-PENDING U.S. APPLICATIONS**

Entire copies of all co-pending applications (or the portion of the application and claims that caused it to be cited) must be sent with the IDS (see 37 CFR 1.98(a)(2)(iii))

<u>Atty. Docket No.</u>	<u>Serial Number</u>	<u>Inventor(s)</u>	<u>Filing Date</u>
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[Only applications that remain pending at the time of submitting this IDS should be listed here. For applications in which patents have issued, the granted patents should be listed on Form PTO/SB08.]



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**SHEET**    1 of 5

Application Number	10/764215
Confirmation Number	
Filing Date	January 23, 2004
First Named Inventor	Chew et al.
Group Art Unit	
Examiner Name	
Attorney Docket Number	P142M

EXAMINER INITIALS*	Cite No. <sup>1</sup>	DOCUMENT NUMBER	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
	1	US-5,744,502	04-28-1998	Lignell et al.	
		US-			
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[illegible]

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<p>Substitute for form 1449A/PTO</p> <p><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b></p> <p>(use as many sheets as necessary)</p> <p>SHEET 2 of 5</p>	<b>COMPLETE IF KNOWN</b>	
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	Confirmation Number	
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	Attorney Docket Number	P142M

### NON PATENT LITERATURE DOCUMENTS

EXAMINER INITIALS*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	2	BASS ET AL., "Normal Canine Lipid Profiles And Effects Of Experimentally Induced Pancreatitis And Hepatic Necrosis On Lipids", Am. J. Vet Res., Vol. 37, No. 11 pg. 1344-1357, 1976	
	3	BENNESEN ET AL., "Treatment Of H. Pylori Infected Mice With Antioxidant Astaxanthin Reduces Gastric Inflammation, Bacterial Load And Modulates Cytokine Release By Splenocytes", Immunology Letters 70, pg. 185-189, (1999)	
	4	JOHN S. BERTRAM, "Carotenoids And Gene Regulation", Nutrition Reviews, Vol. 57, No. 6, pg. 182-191, June 1999	
	5	BJERKENG ET AL., "Bioavailability Of All-E-Astaxanthin And Z-Isomers Of Astaxanthin In Rainbow Trout" Aquaculture, Vol. 157, pg. 63-82, 1997	
	6	GEORGE BRITTON, "Structure And Properties Of Carotenoids In Relation To Function", The FASEB Journal, Vol. 9, pg. 1551-1558, December 1995	
	7	BROWN ET AL., "Plasma carotenoids in normal men after a single ingestion of vegetables or purified β-carotene <sup>1-3</sup> ", Am. J. Clin Nutr., Vol. 49, pg. 1258-1265, 1989	
	8	CHEW ET AL., "Subcellular Distribution Of β-Carotene <sup>1</sup> ", J Anim Sci. Vol. 69 ("Suppl"), pg. 4892-4897, 1991	
	9	CHEW ET AL., "Dietary β-Carotene And Astaxanthin But Not Canthaxanthin Stimulate Splenocyte Function In Mice", Anticancer Research, Vol. 19, pg. 5223-5228, 1999	
	10	BOON P. CHEW, "Antioxidant Vitamins Affect Food Animal Immunity And Health <sup>1,2</sup> ", American Institute Of Nutrition, Vol. 125, pg. 1804S-1808, 1995	
	11	BOON P. CHEW, "The Influence Of Vitamins On Reproduction In Pigs", Recent Advances In Animal Nutrition, pg. 223-239, 1995	
	12	CHEW ET AL., "A Comparison Of The Anticancer Activities Of Dietary β-Carotene, Canthaxanthin And Astaxanthin In Mice In Vivo", Anticancer Research, Vol. 19, pg. 1849-1854, 1999	
	13	CHEW ET AL., "Uptake Of Orally Administered β-Carotene By Blood Plasma, Leukocytes, And Lipoproteins In Calves <sup>1</sup> ", Animal Science, Vol. 71, pg. 730-739, 1993	
	14	CHEW ET AL., "Dietary β-Carotene is Taken Up By Blood Plasma And Leukocytes In Dogs <sup>1</sup> ", The Journal Of Nutrition, Vol. 130, pg. 1788-1791, Jul. 2000	
	15	CHEW ET AL., "Dietary β-Carotene Absorption by Blood Plasma and Leukocytes in Domestic Cats <sup>1</sup> ", The Journal Of Nutrition, Vol. 130, pg. 2322-2325, Sept. 2000	
	16	FLEET ET AL., "Molecular Aspects Of Mineral Metabolism I (192-7)", FASEB J 13(*): A210, 1999	
	17	CORNWELL ET AL., "Studies On The Absorption Of Beta-Carotene And The Distribution Of Total Carotenoid In Human Serum Lipoproteins After Oral Administration", J. Lipid Research, Vol. 3 No. 1, pg. 65-70, January, 1962	
	18	ESTERBAUER ET AL., "The Role Of Vitamin E And Carotenoids In Preventing Oxidation Of Low Density Lipoproteins", Ann NY Academy Science, Vol. 570, pg. 254-267, 1989	
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>	

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	Confirmation Number	
	Filing Date	January 23, 2004
	First Named Inventor	Chew et al.
	Group Art Unit	
	Examiner Name	
	Attorney Docket Number	P142M

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	19	GOULINET ET AL., "Plasma LDL And HDL Subspecies Are Heterogenous In Particle Content Of Tocopherols And Oxygenated And Hydrocarbon Carotenoids", <u>Arteriosclerosis, Thrombosis And Vascular Biology</u> , Vol. 17, pg. 786-796, Apr. 1997	
	20	GUGGER ET AL., "β-Carotene Uptake And Tissue Distribution In Ferrets ( <i>Mustela putorius furo</i> ) <sup>1</sup> ", <u>American Institute Of Nutrition</u> , Vol. 122, pg. 115-119, 1992	
	21	JULIEN ET AL., "Lipoprotein Composition And Transport In The Pig And Dog Cardiac Lymphatic System", <u>Circulation Research</u> , Vol. 49, No. 1, pg. 248-254, July 1981	
	22	JYONOUCHI ET AL., "Immunomodulating Actions Of Carotenoids: Enhancement Of In Vivo And In Vitro Antibody Production To T-Dependent Antigens", <u>Nutrition And Cancer</u> , Vol. 21, pg. 47-58, 1994	
	23	JYONOUCHI ET AL., "Astaxanthin, A Carotenoid Without Vitamin A Activity, Augments Antibody Responses In Cultures Including T-helper Cell Clones And Suboptimal Doses of Antigen <sup>1,2</sup> ", <u>American Institute Of Nutrition</u> , Vol. 125, pg. 2483-2492, 1995	
	24	JYONOUCHI ET AL., "Effect of Carotenoids On In Vitro Immunoglobulin Production By Human Peripheral Blood Mononuclear Cells: Astaxanthin, A Carotenoid Without Vitamin A Activity, Enhances In Vitro Immunoglobulin Production In Response To A T-Dependent Stimulant And Antigen", <u>Nutrition And Cancer</u> , Vol. 23, pg. 171-183, 1995	
	25	JYONOUCHI ET AL., "Antitumor Activity of Astaxanthin and Its Mode of Action", <u>Nutrition And Cancer</u> , Vol. 36(1), pg. 59-65, 2000	
	26	KIM ET AL., "Dietary Lutein Stimulates Immune Response In The Canine", <u>Veterinary Immunology And Immunopathology</u> , Vol. 74, pg. 315-327, 2000	
	27	KIM ET AL., "Modulation Of Humoral And Cell-Mediated Immune Responses By Dietary Lutein In Cats", <u>Veterinary Immunology And Immunopathology</u> , Vol. 73, pg. 331-341, 2000	
	28	KRINSKY ET AL., "The Transport Of Vitamin A And Carotenoids In Human Plasma <sup>1</sup> ", <u>Archives Of Biochemistry And Biophysics</u> , Vol. 73, pg. 233-246, 1958	
	29	KURASHIGE ET AL., "Inhibition Of Oxidative Injury Of Biological Membranes By Astaxanthin", <u>Physiol. Chem. Phys. &amp; Med. NMR</u> , Vol. 22, pg. 27-38, 1990	
	30	WATARU MIKI, "Biological Functions And Activities Of Animal Carotenoids", <u>Pure &amp; Appl. Chem.</u> , Vol. 63, No. 1, pg. 141-146, 1991	
	31	MIYAMOTO ET AL., "Immunological Responses To Polyvalent Canine Vaccines In Dogs", <u>J. Vet. Med. Science</u> , Vol. 57, pg. 347-349, 1995	
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>	

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	32	YOUSRY M. A. NAGUIB, "Antioxidant Activities Of Astaxanthin And Related Carotenoids", <u>J. Agric. Food Chem.</u> , Vol. 48, pg. 1150-1154, 2000	
	33	NAKANO ET AL., "Effect of Astaxanthin Rich Red Yeast ( <i>Phaffia rhodozyma</i> ) On Oxidative Stress In Rainbow Trout", <u>Biochimica et Biophysica Acta</u> , 1426, pg. 119-125, 1999	
	34	LAWLOR ET AL., "Astaxanthin: Antioxidant Effects In Chicken Embryo Fibroblasts", <u>Nutrition Research</u> , Vol. 15, No. 11, pg. 1695-1704, 1995	
	35	MICHELLNE M. MATHEWS-ROTH, "Carotenoids In The Leukocytes Of Carotenemic And Non-Carotenemic Individuals", <u>Clin. Chem.</u> , 24/4, pg. 700-701 (1978)	
	36	MARTIN ET AL., "Anti-and Prooxidant Properties Of Carotenoids", <u>J. Prakt. Chem.</u> , Vol. 341, pg. 302-308, 1991	
	37	NAKANO ET AL., "Improvement Of Biochemical Features In Fish Health By Red Yeast And Synthetic Astaxanthin", <u>J. Agric. Food Chem.</u> , Vol. 43, pg. 1570-1573, 1995	
	38	JAMES ALLEN OLSON, "Absorption, Transport, And Metabolism Of Carotenoids In Humans", <u>Pure &amp; Appl. Chem.</u> , Vol. 88, No. 5, pg. 1011-1016, 1994	
	39	OSTERLIE ET AL., "Accumulation of Astaxanthin All-E, 9Z and 13Z Geometrical Isomers And 3 and 3' RS Optical Isomers In Rainbow Trout ( <i>Oncorhynchus mykiss</i> ) Is Selective <sup>1</sup> ", <u>The Journal Of Nutrition</u> , Vol. 129, pg. 391-398, 1999	
	40	PALOZZA ET AL., "β-Carotene And α-Tocopherol Are Synergistic Antioxidants", <u>Archives Of Biochemistry And Biophysics</u> , Vol. 297, No. 1, August 15 pg. 184-187, 1992	
	41	PARK ET AL., "Dietary Lutein Absorption From Marigold Extract Is Rapid In BALB/c Mice <sup>1,2,3n</sup> ", <u>The Journal Of Nutrition</u> , Vol. 128, pg. 1802-1806, Oct. 1998	
	42	PARK ET AL., "Dietary Lutein But Not Astaxanthin Or β-Carotene Increases <i>pim-1</i> Gene Expression In Murine Lymphocytes", <u>Nutrition And Cancer</u> , Vol. 33, pg. 206-212, 1999	
	43	POOR ET AL., "Evaluation Of The Preruminant Calf As A Model For The Study Of Human Carotenoid Metabolism <sup>1,2n</sup> ", <u>American Institute Of Nutrition</u> , Vol. 122, pg. 262-268, 1992	
	44	ROMANCHIK ET AL., "Distributions Of Carotenoids and α-Tocopherol Among Lipoproteins Do Not Change When Human Plasma Is Incubated In Vitro <sup>1,2,3</sup> ", <u>American Institute Of Nutrition</u> , Vol. 125, pg. 2610-2617, 1995	

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	45	SHIGENAGA ET AL., "Oxidative Damage And Mitochondrial Decay In Aging", <u>Proc. Natl. Acad. Sci.</u> , Vol. 91, pg. 10771-10778, November 1994	
	46	TANAKA ET AL., "Chemoprevention Of Mouse Urinary Bladder Carcinogenesis By The Naturally Occurring Carotenoid Astaxanthin", <u>Carcinogenesis</u> , Vol. 15 No. 1, pg. 15-19, 1994	
	47	TERPSTRA ET AL., "Improved Techniques For The Separation Of Serum Lipoproteins By Density Gradient Ultracentrifugation: Visualization By Presenting And Rapid Separation Of Serum Lipoproteins From Small Volumes Of Serum", <u>Analytical Biochemistry</u> , Vol. 111, pg. 149-157, 1981	
	48	FLEET ET AL., "Molecular Aspects Of Mineral Metabolism I (192.7)" <u>Faseb J</u> , Vol. 13, A210 1999	
	49	J. TERAQ, "Antioxidant Activity of $\beta$ -Carotene-Related Carotenoids In Solution", <u>Lipids</u> , Vol. 24; pg. 659-661, 1989	
	50	JOHN H. WEISBURGER, "Nutritional Approach To Cancer Prevention With Emphasis On Vitamins, Antioxidants, And Carotenoids <sup>1-3</sup> ", <u>Am. J. Clin. Nutr.</u> , Vol. 53, pg. 226S-237S, 1991	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

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